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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/030,453	08/02/2002	Patrick C. Kung	044574-5040-01	5710
9629	7590	08/05/2004	EXAMINER	
MORGAN LEWIS & BOCKIUS LLP 1111 PENNSYLVANIA AVENUE NW WASHINGTON, DC 20004			ZEMAN, MARY K	
			ART UNIT	PAPER NUMBER
			1631	

DATE MAILED: 08/05/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

10/030,453

Applicant(s)

KUNG ET AL.

Examiner

Mary K Zeman

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☐ Responsive to communication(s) filed on ____.
- 2a) ☐ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-24 is/are pending in the application.
- 4a) Of the above claim(s) ____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) ____ is/are allowed.
- 6) ☐ Claim(s) ____ is/are rejected.
- 7) ☐ Claim(s) ____ is/are objected to.
- 8) ☒ Claim(s) 1-24 are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on ____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. ____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- ☐ Notice of References Cited (PTO-892)
- ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date ____.
- ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date. ____.
- ☐ Notice of Informal Patent Application (PTO-152)
- ☐ Other: ____.

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DETAILED ACTION

The Group and/or Art Unit location of your application in the PTO has changed. To aid in correlating any papers for this application, all further correspondence regarding this application should be directed to Group Art Unit 1631.

Claims 1-24 are pending in this application.

This application is a National Stage Application of International Application PCT US01/07608, filed under the provisions of 35 USC 371, therefore, Lack of Unity practice is proper.

Lack of Unity

This application contains the following inventions or groups of inventions which are not so linked as to form a single general inventive concept under PCT Rule 13.1.

With respect to unity of invention PCT Rule 13.1 states:

The international application shall relate to one invention only or to a group of inventions so linked as to form a single general inventive concept ("requirement of unity of invention").

Additionally, PCT Rule 13.2 states:

Unity of invention exists only when there is a technical relationship among the claimed inventions involving one or more special technical features. The term "special technical features" is defined as meaning those technical features that define a contribution which each of the inventions considered as a whole, makes over the prior art.

With regard to the application of PCT Rule 13, 37 CFR §1.475 concerning unity of invention states:

- (a) An international and a national stage application shall relate to one invention only or to a group of inventions so linked as to form a single general inventive concept ("requirement of unity of invention"). Where a group of inventions is claimed in an application, the requirement of unity of invention shall be fulfilled only when there is a technical relationship among those inventions involving one or more of the same or corresponding special technical features. The expression "special technical features" shall mean those technical features that define a contribution which each of the claimed inventions, considered as a whole, makes over the prior art.
- (b) An international or a national stage application containing claims to different categories of invention will be considered to have unity of invention if the claims are drawn only to one of the following combinations of categories:
 - (1) A product and a process specially adapted for the manufacture of said product; or
 - (2) A product and a process of use of said product; or
 - (3) A product, a process specially adapted for the manufacture of the said product, and a use of the said product; or
 - (4) A process and an apparatus or means specifically designed for carrying out the said process; or
 - (5) A product, a process specially adapted for the manufacture of the said product, and an apparatus or means specifically designed for carrying out the said process.

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(c) If an application contains claims to more or less than one of the combinations of categories of invention set forth in paragraph (b) of this section, unity of invention might not be present.

(d) If multiple products, processes of manufacture or uses are claimed, the first invention of the category first mentioned in the claims of the application and the first recited invention of each of the other categories related thereto will be considered as the main invention in the claims, see PCT Article 17(3)(a) and 1.476(c).

(e) The determination whether a group of inventions is so linked as to form a single general inventive concept shall be made without regard to whether the inventions are claimed in separate claims or as alternatives within a single claim.

Group I, claim(s) 1-12 drawn to a method of establishing a standardized Herbal BioResponse Array (HBR Array) and a method of evaluating an herbal composition using that standardized array. The HBR array comprises marker data indicative of changes in gene expression.

Group II, claim(s) 13-15 drawn to a second method of using the standardized array, in a method to determine if an herbal composition meets a standard specification.

Group III, claims 16-19 drawn to a third method of using the standardized array, in a method of adjusting the components of an herbal composition to meet a standard in a standardized array.

Group IV, claims 20, drawn to a method of predicting the biological activity of an herbal composition by comparison with a "differential response measurement" HBR Array. This array comprises information regarding the differential response of two or more markers in response to a test.

Group V, claims 21, drawn to a method of measuring the relatedness of an herbal composition to a characterized herbal composition utilizing the "differential response measurement" HBR Array.

Group VI, claims 22, drawn to a method of predicting new therapeutic application of an herbal composition using the "differential response measurement" HBR Array.

Group VII, claims 23-24, drawn to a method of determining the gene expression profile induced by an herbal composition.

The inventions listed as Groups I -VII do not relate to a single general inventive concept under PCT Rule 13.1 because, under PCT Rule 13.2, they lack the same or corresponding special

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technical features for the following reasons: The asserted special technical feature appears to be the Standardized Herbal BioResponse Array. This Array is created by the method of Group I, and used in the methods of Groups II-VII. However, the creation and use of the Standardized Herbal BioResponse Array is not a novel contribution over the art, and therefore cannot qualify as the special technical feature linking all the inventions. For example, WO 97/13877, cited in the international search report and on an information disclosure statement, disclose the creation of an array of information regarding markers indicative of changes in gene expression in response to a test. WO 00/24934 cited in the international search report and on an information disclosure statement, also disclose the creation of an array of information regarding markers indicative of changes in gene expression in response to a test. Further, WO 99/58720 cited in the international search report and on an information disclosure statement, disclose the creation of an array of information regarding markers indicative of changes in gene expression in response to a test. The International search report also lists the following documents which are evidence that the claims are not a novel contribution over the art: WO 98/06874, WO 97/27317; WO 97/06277; WO 97/22720; WO 99/44062 and GRAY et al. (1998) SCIENCE. Further, Each of the methods of using that array (Groups I-VII) have differing steps leading to differing ultimate goals, requiring the collection, and analysis of differing data to differing ends. Therefore the methods of using the array are not a special technical feature linking all the groups.

Therefore the creation of HBR Arrays and methods for their use are not a special technical feature as defined in PCT Rule 13.2.

Applicant is advised that the response to this requirement to be complete must include an election of the invention to be examined even though the requirement be traversed (37 CFR 1.143).

Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a diligently-filed petition under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(h).

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Any inquiry concerning this communication or earlier communications from the examiner should be directed to Mary K Zeman whose telephone number is (571) 272 0723

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Michael P Woodward can be reached on (571) 272 0722. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to (571) 272-0547.

Patent applicants with problems or questions regarding electronic images that can be viewed in the Patent Application Information Retrieval system (PAIR) can now contact the USPTO's Patent Electronic Business Center (Patent EBC) for assistance. Representatives are available to answer your questions daily from 6 am to midnight (EST). The toll free number is (866) 217-9197. When calling please have your application serial or patent number, the type of document you are having an image problem with, the number of pages and the specific nature of the problem. The Patent Electronic Business Center will notify applicants of the resolution of the problem within 5-7 business days. Applicants can also check PAIR to confirm that the problem has been corrected. The USPTO's Patent Electronic Business Center is a complete service center supporting all patent business on the Internet. The USPTO's PAIR system provides Internet-based access to patent application status and history information. It also enables applicants to view the scanned images of their own application file folder(s) as well as general patent information available to the public.

For all other customer support, please call the USPTO Call Center (UCC) at 800-786-9199.


MARY K. ZEMAN
PRIMARY EXAMINER
